

6, lines 15-19 ("Recombinant human Erythropoietin...was administered...for 6 weeks") and in TABLE II on page 10 which shows values "after 3 and 6 weeks of treatment."

Applicants thank the Examiner for the courtesies extended to Applicant's representatives during a March 28, 2001 personal interview, during which the outstanding rejections were discussed. The remainder of Applicant's separate record of the substance of the interview is contained in the remarks below.

#### **OBJECTION TO THE SPECIFICATION**

The Office Action objects to the specification for containing asserted informalities. Applicant believes that this rejection is overcome with the above-amended section of the specification. Reconsideration and withdrawal of the objection to the specification are respectfully requested.

#### **SECTION 112, FIRST PARAGRAPH, REJECTIONS**

The Office Action rejects claims 14-16, 20-22, 25, 26 and 31 under 35 U.S.C. 112, first paragraph, as assertedly containing subject matter not sufficiently described in the specification. As was agreed during the March 28, 2001 personal interview, the above-amendment of the claims to recite --3 to 6 weeks-- overcomes this rejection. Reconsideration and withdrawal of the rejection of claims 14-16, 20-22, 25, 26 and 31 under 35 U.S.C. 112, first paragraph, are respectfully requested.

The Office Action also rejects claims 14-16 and 21-22 under 35 U.S.C. 112, first paragraph, as assertedly containing subject matter not sufficiently described in the specification. Claims 14-16 and 21-22 are canceled, rendering this rejection moot.

Reconsideration and withdrawal of the rejection of claims 14-16 and 21-22 under 35 U.S.C. 112, first paragraph, are respectfully requested.

### **SECTION 102/103 REJECTIONS**

The Office Action rejects claims 18-20 and 23-26 under 35 U.S.C. 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. 103(a) as being obvious over Toshihide et al. or Pettersson et al. Applicant traverses these rejections as they may apply to the amended claims, since both of these papers describe the effect of EPO on the treatment of anaemia, while the present claims are directed to a new method of alleviating the effects on the joint disease problems of rheumatoid arthritis patients.

In particular, the Toshihide et al. abstract teaches "a trial of rHuEPO in 13 rheumatoid patients scheduled for elective orthopedic replacement procedures ... for 2 or 3 weeks...[and] all patients who received replacement surgery...showed increase in erythropoieses..." As the Office Action notes, Toshihide et al. does not teach or suggest that the patients experienced a decrease in stiffness, pain or swelling, an increase in grip strength, or change in C-protein sedimentation rates. However the Office Action asserts that the treatment taught in Toshihide et al. and the present claimed invention appear to be the same or similar.

It appears that Toshihide is directed to a method of accomplishing autologous blood donation and orthopedic replacement surgery and not to a method for treating symptoms or disease activity. Furthermore, nowhere does Toshihide et al. teach or suggest that any of the 13 patients that apparently received replacement surgery had any of the symptoms or disease activity required by the present claims.

Pettersson teaches treatment of anemia of rheumatoid arthritis with subcutaneously administered recombinant human erythropoietin. The Office Action asserts that while "Pettersson et al does not specifically teach that the patients experienced a decrease in [morning] stiffness, pain or swelling,..., Applicant is reminded that silence about a particular feature does not constitute its absence."

However, Applicants respectfully note that Pettersson et al is not silent regarding such features. Pettersson et al. state that at "the beginning and at the end of the 24-week study the patients went through a thorough clinical evaluation. Duration of morning stiffness and severity of joint pain were evaluated..." (see the first full paragraph in the second column of page 189 of Pettersson). Pettersson et al. further teaches that "there was no significant change in our patients' joint status" (see the first full paragraph in the first column of page 192 of Pettersson).

Thus, since Pettersson et al. teach that morning stiffness and severity of joint pain are not treated by their procedures, we believe that Pettersson et al. clearly does not teach or suggest treating such symptoms as morning stiffness pain, loss of grip strength, painful joints and swollen joints (or of ameliorating a disease activity of erythrocyte sedimentation rate or C-reactive protein level, as in the presently claimed invention.


For at least the above reasons, reconsideration and withdrawal of the rejection of claims 18-20 and 23-26 under 35 U.S.C. 102(b) or under 35 U.S.C. 103(a) are respectfully requested.

**CONCLUSION**

Applicant respectfully submits that this application is in condition for allowance and such action is earnestly solicited. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicant's undersigned representative at the telephone number listed below to schedule a personal or telephone interview to discuss any remaining issues.

Please charge any fee deficiency or credit any overpayment to Deposit Account No. 01-2300.

Respectfully submitted,

A handwritten signature in black ink, reading "Robert K. Carpenter". The signature is fluid and cursive, with a horizontal line extending from the end of the name.

Robert K. Carpenter  
Registration No. 34,794

ARENT FOX KINTNER PLOTKIN & KAHN, PLLC  
1050 Connecticut Avenue, N.W.,  
Suite 600  
Washington, D.C. 20036-5339  
Tel: (202) 857-6000  
Fax: (202) 638-4810

## **MARKED-UP AMENDMENTS**

### **IN THE SPECIFICATION**

The specification is amended in the paragraph on page 4, lines 1-3, as follows:

--Also, it will be necessary to ensure that no hypertension occurs at a detrimental level [leval]. Ways to avoid such a reaction are also well known in the art.--

### **IN THE CLAIMS**

18. (Four Times Amended) A method of treating a symptom associated with rheumatoid arthritis in a patient in need of such treatment, comprising administering to the patient a rheumatoid arthritis symptoms treating effective amount of erythropoietin over a treatment period, wherein said treatment period is 3 to [or] 6 weeks, wherein said symptom is at least one symptom selected from the group consisting of morning stiffness pain, loss of grip strength, painful joints, and swollen joints.

20. (Four Times Amended) A method of ameliorating a disease activity of rheumatoid arthritis in a patient in need of such amelioration, comprising administering to the patient a rheumatoid arthritis disease activity ameliorating effective amount of erythropoietin over a period, wherein said period comprises 3 to 6 weeks of treatment, wherein said disease activity is an erythrocyte sedimentation rate or C-reactive protein level.

30. (Twice Amended) A method of treating a symptom associated with rheumatoid arthritis in a patient in need of such treatment, comprising administering to the patient a rheumatoid arthritis symptoms treating effective amount of erythropoietin over a treatment period, wherein said treatment period is 3 to 6 weeks, wherein said symptom is at least one symptom selected from the group consisting of morning stiffness, pain, loss of grip strength, painful joints, and swollen joints.